IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ELI LILLY AND COMPANY and, THE TRUSTEES OF PRINCETON UNIVERSITY	)	
Plaintiffs,	)	Civil Action No. 08-335-GMS
v.	)	
TEVA PARENTERAL MEDICINES, INC.	)	
Defendant.	)	

AMENDED ANSWER OF DEFENDANT
TEVA PARENTERAL MEDICINES, INC.

Defendant, Teva Parenteral Medicines, Inc. ("Teva") hereby answers the Complaint filed by Eli Lilly and Company ("Eli Lilly") and The Trustees Of Princeton University ("Princeton") (collectively referred to as "Plaintiffs"), as follows:

1. Teva admits that the Complaint purports to state an action that arises under the patent laws of the United States, Title 35, United States Code. Teva further admits that Teva filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell Pemetrexed Disodium for Injection, Eq. 500 mg Base/Vial, a generic version of ALIMTA®, prior to the expiration of U.S. Patent No. 5,344,932 ("the '932 patent"). Teva denies the remaining allegations in paragraph 1 of the Complaint.

PARTIES

2. On information and belief, Teva admits the allegations in paragraph 2 of the Complaint.

3. On information and belief, Teva admits the allegations in paragraph 3 of the Complaint.

4. Teva admits the allegations in paragraph 4 of the Complaint.

JURISDICTION AND VENUE

5. Teva admits that subject matter jurisdiction in this Court is proper pursuant to 28 U.S.C. §§ 1331 and 1338(a). Teva admits that Teva is subject to personal jurisdiction in Delaware. For the purpose of this case only, Teva also admits that venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). Teva denies the remaining allegations in paragraph 5 of the Complaint.

BACKGROUND

6. Upon information and belief, Teva admits that ALIMTA® is indicated in combination with cisplatin for the treatment of patients with malignant pleural mesothelioma whose disease is either unresectable or who are otherwise not candidates for curative surgery. Upon information and belief, Teva also admits that ALIMTA® as a single-agent is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after prior chemotherapy. Teva denies the remaining allegations in paragraph 6 of the Complaint.

7. Upon information and belief, Teva admits the allegations in paragraph 7 of the Complaint.

COUNT 1
U.S. PATENT NO. 5,344,932

8. In response to the allegations contained in paragraph 8 of the Complaint, Teva realleges paragraphs 1-7 as if fully set forth herein.

9. Teva admits that according to the face of the '932 patent, the '932 patent is entitled "N-(pyrrolo(2,3-d)pyrimidin-3-ylacyl)-Glutamic Acid Derivatives" and issued on

September 6, 1994. Teva also admits that according to the face of the '932 patent, the '932 patent issued to Princeton as assignee of Edward C. Taylor. Teva further admits that what appears to be a true and correct copy of the '932 patent was attached to the Complaint as Exhibit A. Teva denies the remaining allegations in paragraph 9 of the Complaint.

10. Teva is without information sufficient to admit or deny that Princeton owns the '932 patent and therefore denies the same. Teva denies the remaining allegations in paragraph 10 of the Complaint.

11. Teva is without information sufficient to admit or deny that Lilly has been granted an exclusive license under the '932 patent and therefore denies same. Teva denies the remaining allegations in paragraph 11 of the Complaint.

12. Teva is without information sufficient to admit or deny that ALIMTA® is covered by one or more claims of the '932 patent and therefore denies the same. Upon information and belief, Teva admits the remaining allegations in paragraph 12 of the Complaint.

13. Teva admits that by letter dated April 24, 2008 ("the Notice Letter"), Teva notified Plaintiffs that Teva had submitted to the FDA an ANDA, No. 90-352, for Teva's Pemetrexed Disodium for Injection, Eq. 500 mg Base/Vial ("Teva's ANDA Product"), a drug product that is a generic version of ALIMTA®. Teva also admits that Teva submitted ANDA No. 90-352 to FDA under the provisions of 21 U.S.C. § 355(b) seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product prior to the expiration of the '932 patent. Teva denies the remaining allegations in paragraph 13 of the Complaint.

14. Teva admits that in the Notice Letter, Teva notified Plaintiffs that, as part of its ANDA, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of

the FDCA, 21 U.S.C. § 355 (j)(2)(A)(vii)(IV), with respect to the '932 patent. Teva further admits that Teva submitted ANDA No. 90-352 to FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the '932 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, or sale of Teva's ANDA Product. Teva denies the remaining allegations in paragraph 14 of the Complaint.

15. Teva denies the allegations in paragraph 15 of the Complaint to the extent they allege that Teva's ANDA Product is covered by any valid or enforceable claim of the '932 patent.

16. Teva admits the allegations in paragraph 16 of the Complaint.

17. Teva admits that Teva filed ANDA No. 90-352 for the purpose of obtaining approval from FDA to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product prior to the expiration of the '932 patent. Teva denies the remaining allegations in paragraph 17 of the Complaint to the extent they allege that Teva's ANDA Product is covered by any valid or enforceable claim of the '932 patent.

18. Teva denies the allegations in paragraph 18 of the Complaint to the extent they allege that Teva's ANDA Product is covered by any valid or enforceable claim of the '932 patent.

19. Teva admits that Teva filed ANDA No. 90-352 for the purpose of obtaining approval from FDA to engage in the manufacture, use, offer for sale, and/or sale of Teva's ANDA Product prior to the expiration of the '932 patent. Teva is without information sufficient to admit or deny that Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product immediately and imminently upon approval of ANDA No. 90-352 and therefore denies the same.

20. Teva denies the allegations in paragraph 20 of the Complaint to the extent they allege that Teva's ANDA Product is covered by any valid or enforceable claim of the '932 patent.

21. Teva admits that Teva filed ANDA No. 90-352 for the purpose of obtaining approval from FDA to engage in the manufacture, use, offer for sale, and/or sale of Teva's ANDA Product prior to the expiration of the '932 patent. Teva is without information sufficient to admit or deny that Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-352 and therefore denies the same.

22. Teva admits that Teva filed ANDA No. 90-352 for the purpose of obtaining approval from FDA to engage in the manufacture, use, offer for sale, and/or sale of Teva's ANDA Product prior to the expiration of the '932 patent. Teva is without information sufficient to admit or deny that Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product immediately and imminently upon approval of ANDA No. 90-352 and therefore denies the same. Teva denies the allegations in paragraph 22 of the Complaint to the extent they allege that Teva's ANDA Product is covered by any valid or enforceable claim of the '932 patent. Teva denies that Teva plans and intends to, and will, actively induce infringement of the '932 patent when its ANDA is approved.

23. Teva admits that Teva filed ANDA No. 90-352 for the purpose of obtaining approval from FDA to engage in the manufacture, use, offer for sale, and/or sale of Teva's ANDA Product prior to the expiration of the '932 patent. Teva is without information

sufficient to admit or deny that Teva will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 90-352 and therefore denies the same. Teva denies the allegations in paragraph 23 of the Complaint to the extent they allege that Teva's ANDA Product is covered by any valid or enforceable claim of the '932 patent. Teva denies knowledge that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '932 patent. Teva further denies that Teva'a ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Teva further denies that Teva plans and intends to, and will, contribute to infringement of the '932 patent upon approval of ANDA No. 90-352.

24. Teva denies the allegations in paragraph 24 of the Complaint to the extent they allege that Teva's ANDA Product is covered by any valid or enforceable claim of the '932 patent.

25. Teva denies the allegations in paragraph 25 of the Complaint.

26. Teva denies the allegations in paragraph 26 of the Complaint.

27. Teva denies each and every allegation contained in the Complaint not expressly admitted above.

ANSWER TO PRAYER FOR RELIEF

28. Teva denies that Plaintiffs are entitled to the judgment and relief prayed for in paragraphs (a) through (g) of the Complaint.

FIRST AFFIRMATIVE DEFENSE

29. The manufacture, use, offer for sale, sale or importation of Teva's ANDA Product that is the subject of ANDA No. 90-352 does not and will not infringe any valid or enforceable

claim of the '932 patent.

SECOND AFFIRMATIVE DEFENSE

30. All of the claims of the '932 patent that could be asserted against Teva based on Teva's ANDA No. 90-352 are invalid under 35 U.S.C. § 103 since the differences between the subject matter of the claims of the '932 patent and the relevant prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art to which said subject matter pertains.

THIRD AFFIRMATIVE DEFENSE

31. One or more claims of the '932 patent that could be asserted against Teva based on Teva's ANDA No. 90-352 are invalid under 35 U.S.C. § 112, since they fail to satisfy the requirements for a proper dependent claim.

FOURTH AFFIRMATIVE DEFENSE

32. All of the claims of the '932 patent that could be asserted against Teva based on Teva's ANDA No. 90-352 are invalid under the doctrine of obviousness-type double patenting since the claimed invention is an obvious modification of inventions claimed in commonly owned U.S. Patent Nos. 4,996,206 and 5,028,608 in light of the relevant prior art.

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Dated: July 15, 2008

CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire, hereby certify that on July 15, 2008, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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I further certify that on July 15, 2008, I caused a copy of the foregoing document to be served by e-mail and hand delivery on the above-listed counsel of record and on the following in the manner indicated:

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